

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Susan WIMER-MACKIN Confirmation No.: 5685
Serial No.: 10/589,290 Group Art Unit: 1645
Filed: August 11, 2006 Examiner: Patricia Ann Duffy
For: ANTHRAX ANTIGENS AND METHODS OF USE

DECLARATION UNDER 37 C.F.R. § 1.131

I, Susan Kagel declare as follows:

1. I am the named inventor of the above-identified U.S. Application No. 10/589,290 (the '290 application), previously Susan Wimer-Mackin.
2. I understand that a publication to Miksztra *et al.* (Journal of Infectious Diseases, Vol. 191: 278-288, January 15, 2005) has been cited as prior art in the above-identified application and allegedly discloses dry powder formulations of recombinant protective antigen, CpG, trehalose, and chitosan loaded into capsules for intranasal delivery with a device.
3. I understand that Miksztra *et al.* was published electronically on December 15, 2004. I also understand that the Examiner has deemed that some of the claims are entitled to a priority date of February 11, 2005, the filing date of the '290 application.
4. The subject matter of the pending claims (*e.g.*, dry powder compositions comprising anthrax antigens) was invented by me (the named inventor) prior to December 15, 2004.
5. Example 5, for instance, of the present application describes dry powder formulations of vaccine compositions comprising protective antigen and their effectiveness in inducing a protective immune response in rabbits when administered intranasally using a powder

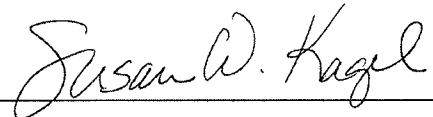
administration device. Tables 12, 13, and 15 describe four dry powder compositions (**D1, D3, D5, and D6**) in comparison to two liquid formulations (L8 and L10) in inducing an immune response to anthrax in rabbits.

6. Exhibits A and B, dated before December 15, 2004, are pages from the laboratory notebook of Sarah J. Warwood, who was working under my direction at the time. Exhibit A sets forth the experimental protocol for testing the dry powder formulations in eliciting protective immunity against anthrax in rabbits. This protocol is identical to the experiment disclosed in Example 5 in the instant application. Exhibit B depicts the execution of this protocol and describes the dose and route of administration of each formulation.

7. Thus, Exhibits A and B document the production of the identical dry powder compositions described in Example 5 of the present application and immunization of rabbits with such compositions before December 15, 2004.

8. I further declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Respectfully submitted,



Susan Kagel

November 11, 2009
Date

EXHIBIT A

144 PROJECT NO.

BOOK NO.

TITLE

Work continued from Page _____

Proof of principal experiments for West Pharm. And LigoCyte

BD601.132

Experiment 3. (Experiments 1 and 2 done in-house at LigoCyte.)

Objective: To determine if intranasal powder formulations of PA and MPL with chitosan can protect rabbits against virulent anthrax challenge.

5

rabbits Formulation Treatment

5	D1	Negative control
10	D3	PA+MPL+Chitosan (high dose)+ Caps10 conj
10	D5	PA+MPL+Chitosan (high dose)+Caps10
10	D6	Dry PA+MPL + Caps10 conj (no chitosan)
10	L8	PA+MPL+ Caps10 conj
10	L10	AVA

10

55 rabbits (female, NZW) will be used. All immunizations will be intranasally, except for AVA which will be given i.m. (AVA is included as it is the standard anthrax vaccine that is known to protect via adaptive immunity.) PA dose will be 90 µg and MPL 25 µg. Rabbits will be immunized at 0 and 4 weeks. Serum will be collected at 0, 4 and 8 weeks. Nasal washes collected at 8 weeks. Animals will then be shipped to Ft. Detrick, MD for aerosol challenge with virulent anthrax spores. Animals that are still alive 2 weeks post-challenge will be deemed protected. (Note: We may not be able to get all animals into challenge due to space restraints at the challenge facility. If that is the case, we could challenge less of each group.) Serum and nasal washes will be analyzed for anti-PA and anti-capsule IgG and IgA responses.

15

- start

- spray device to mark

20

25

www.scientificbindery88yrs.com

Work continued to Page _____

SIGNATURE

Sarah J. Demmons

DATE

DISCLOSED TO AND UNDERSTOOD BY

DATE

WITNESS

SB

DATE

EXHIBIT B

TITLE

Work continued from Page

PROJECT NO. 601

161

BOOK NO. SJ10009083

Vacc 132 Day 0

Preparations of Vaccines West 20mg, IN 200µl, IM 100µl, Buffer 150mM NaCl

Group 1 – Group 4 provided in spray device from West Pharmaceuticals

Group 5 PA 90µg + MPLaf 25µg + conj caps10mer 90µg
10 rabbits IN

10+2extra = 12 x 200µl = 2.4ml

108µl of PA (10mg/ml)

+300µl MPL(1mg/ml)

+ µl conj caps10mer

+ µl buffer

→ pg 167

Group 6 PA 90µg/MPLaf 25µg 10 rabbits IM

10+2extra = 12 x 100µl = 1.2ml

✓ 108µl of PA (10mg/ml)

✓ +300µl MPL(1mg/ml)

✓ + 792µl buffer

JS

BD601.132

PA/Chitosan West Pharmaceuticals Dry Formulations

Vaccine

Delivery

Group 1 Neg control (Dry West) D1 5 rabbits Sprayer

Group 2 PA + MPLaf + Chitosan + conj caps10mer D3
(Dry West) 10 rabbits Sprayer

Group 3 PA 90µg/Chitosan/MPLaf 25µg + caps10mer D5
(Dry West) 10 rabbits Sprayer

Group 4 PA + MPL + conj caps10mer D6
(Dry West) 10 rabbits Sprayer

Group 5 PA 90µg + MPLaf 25µg + 90µg conj caps10mer
(Liquid Ligocyte) 10 rabbits IN

Group 6 PA 90µg + MPLaf 25µg 10 rabbits IM

55 Rabbits NZ White Females

Day 0 – Vaccinate and Bleed

4 Week - Boost and Bleed

8 Week - Bleed

12 Week - Terminal bleed and BAL

Work continued to Page

SIGNATURE

Sivali J. W. G. M. M. A.

DATE

DISCLOSED TO AND UNDERSTOOD BY

DATE

WITNESS

DATE

JS

166/167